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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,256	12/09/2003	John Gavin MacDonald	KCX-859 (19100)	4720
22827	7590	10/07/2005	EXAMINER	
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			STITZEL, DAVID PAUL	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,256

Applicant(s)

MACDONALD ET AL.

Examiner

David P. Stitzel, Esq.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

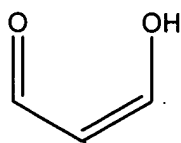
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|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

PD

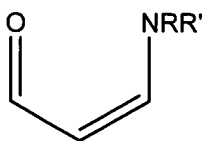
OFFICIAL ACTION***Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺, 469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:

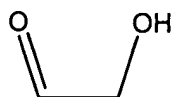


- II. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺, 469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:

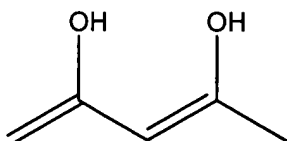


- III. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺,

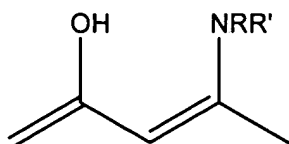
469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:



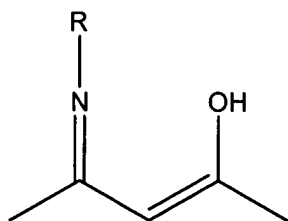
- IV. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺, 469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:



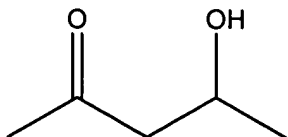
- V. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺, 469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:



- VI. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺, 469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:

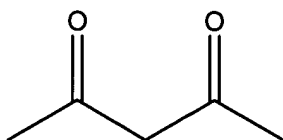


- VII. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺, 469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:

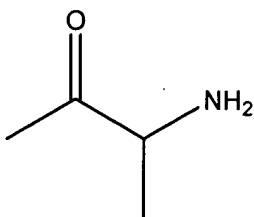


- VIII. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺,

469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:



- IX. Claims 4, 5, 15 and 26 are drawn to a triggerably releasable delivery system comprising alumina containing particles (as classified in class 424, subclass 457⁺, 469⁺ and 489⁺) having a functional compound bound thereto and a method of utilizing said triggerably releasable delivery system for the treatment of a patient, wherein said functional compound prior to bonding to said alumina particle contains a chemical moiety comprising:



- X. Claims 25 and 27 are broadly drawn to a triggerably releasable delivery system comprising an inorganic particle, without any specific reference to alumina (as classified in class 424, subclass 457⁺, 469⁺ and 489⁺), having a functional compound bound thereto.

Claims 1-3, 6-14 and 16-24 link Inventions I-IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, namely claims 1-3, 6-14 and 16-24. Likewise, upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from, or otherwise including all of the limitations of, the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from, or including all of the limitations of, the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 170 USPQ 129, 131-32 (CCPA 1971); and MPEP § 804.01.

Inventions I through IX are drawn to a triggerably releasable delivery system comprising alumina containing particles, with each of the aforementioned respective Inventions having a different functional compound, characterized by a distinct chemical moiety, bound to said alumina particles.

Invention X is drawn to a product comprising an inorganic particle and is related to Inventions I-IX, which are drawn to a product comprising inorganic alumina containing particles and a method of using said product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the method for using the product as claimed can be practiced with another materially different product; or (2) that the product as claimed can be used in another materially different method of using said product (MPEP § 806.05(h)). In the instant

case, the triggerably releasable delivery system as claimed in Invention X can be utilized in methods that are materially different from the methods claimed in Inventions I-IX. For example, as opposed to treating a patient, a triggerably releasable delivery system comprising an inorganic particle may alternatively be utilized as a contrast imaging reagent, as described in the Mohnot '003 patent (column 3, lines 43-47).

Because these inventions are distinct for the reasons given above and the search required for Group X is not required for Groups I-IX, restriction for examination purposes as indicated is proper.

Conclusion to Restriction Requirement

The Examiner has required restriction between product and methods of use claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn methods of use claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of use claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. If claims are added after the election, Applicants must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that a fully responsive reply to this requirement must include an explicit identification of the specific species that is elected consonant with this requirement, and a listing of all claims, including any claims subsequently added thereto, which are

readable upon the elected species. Generic claims that are not listed by the Applicants as being readable upon the elected species will be withdrawn from prosecution on the merits. An argument that a claim is allowable or that claims are not generic is considered nonresponsive unless accompanied by an election of a specific species. See 37 C.R.R. § 1.143. Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

Upon the allowance of a generic claim, Applicants will be entitled to a consideration of claims that are directed to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of use claims will be withdrawn, and the rejoined methods of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of use claims may be maintained. Withdrawn methods of use claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the methods of use claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Contact Information

A telephone call was made to Ms. Christina Mangelsen on September 22, 2005, to request an oral election. See, MPEP § 812.01. However, an oral election did not result therefrom, thereby necessitating that the instant written restriction requirement be mailed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The examiner can normally be reached on Monday-Friday, from 7:00AM-5:30PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached at 571-272-0887. The central fax number for the USPTO is 571-273-8300.

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Examiner: David P. Stitzel, Esq.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.


JOHN PAK
PRIMARY EXAMINER
GROUP 1600